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FOR

SYSTEM AND APPARATUS FOR THE DISPENSING OF DRUGS

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BACKGROUND AND SUMMARY OF THE INVENTION

The present invention relates generally to the dispensing of items, such as drugs, and more particularly, a system and apparatus for the dispensing of items such as drugs, including an apparatus for storing, transporting, receiving, refilling, and tracking drugs through their channels of distribution.

It is known in the art to dispense drugs at a healthcare location or other care facility through an automated dispensing machine, for example, such as the one described in U.S. Patent No. 5,014,875. The entire contents of U.S. Patent No. 5,014,875 are hereby incorporated by reference herein. As described in that patent, a pharmacist or pharmacist technician arranges for drugs to be moved to each automated dispensing machine and be manually placed into drawers, and more particularly, pockets within those drawers for later removal and administration by doctors and nursing staff. The patent referred to above describes the benefits of such an approach, as well as the drawbacks of previously known systems for accomplishing similar purposes.

The apparatus of the present invention comprises a unique receptacle having a bottom and a plurality of sides and an attached top that may be actuated to open to expose the contents of

the receptacle. The receptacle further includes an information storage device, such as a memory chip, for storing information regarding the contents of the receptacle.

In a preferred embodiment, the receptacle includes an electronic actuated latch for the top opening that opens upon receipt of required information to be inputted by an operator. The latch affords a safety solution for the receptacle through the entire process of medication distribution, that an unauthorized person cannot gain access to the receptacle other than by vandalizing the receptacle.

The unique receptacle of the present invention may be adapted to reside in an automated dispensing machine along with a plurality of other like receptacles. The receptacles are preferably configured in such a way to allow for an efficient and optimum placement within the dispensing machine for access by an operator, such as a nurse or doctor or other authorized individual. In this embodiment, each receptacle preferably contains individual packages of particular drugs, drug kits, medical supplies, or combinations of these. Individual receptacles may have multiple types of drugs or medical supplies for one particular patient or a plurality of the same type of drug or medical supply for use with several patients. In this embodiment of the invention, the receptacles each contain associated hardware to support information about the contents of the receptacle in the automated dispensing machine. Likewise, the data entry device associated with the automated dispensing machine enables an operator to enter certain requested information, such as operator identification information or requested drug information or patient identification information, which will then be electronically transmitted to the appropriate receptacle within the automated dispensing machine which actuates the latch to open the top of the appropriate receptacle for access by the operator. All of the information for these

transactions are maintained by the system, so that a record of the operator, patient, drug requested, receptacle accessed, etc. is available.

In another embodiment of the present invention, a system is described in which the receptacles are loaded with particular items at a batch facility then "programmed" with a memory chip containing information. Information about the items loaded into each receptacle may be stored in information storage devices that may be integral to each receptacle and/or information about the items loaded into each receptacle may be put in bar code form on a bar code label and placed on the receptacle. The receptacles with the items now contained within them are then closed and transported to a receiving station, such as a pharmacy at a healthcare facility. There, information regarding the contents of each receptacle may be obtained from the receptacle's information storage device. In another embodiment, information regarding the contents of each receptacle may be scanned with a hand-held scanner reading a bar code label that was placed on each receptacle at the batch facility. Data obtained from the information storage device and/or from scanning the bar code labels may be stored in a computer at the receiving station for inventory control purposes. The same computer at the receiving station may be in communication with automated dispensing machines, even though the automated dispensing machines may be at a remote location from the receiving station computer. As users/operators of the automated dispensing machine enter information to gain access to the contents of the receptacles within the automated dispensing machine, the operator-entered information may be delivered to the receiving station computer to maintain a real-time inventory of each receptacle in each automated dispensing machine. The receptacle's information storage device may also

maintain real-time inventory of the receptacle's contents as users/operators gain access to the contents of the receptacle.

In another embodiment of the present invention, a manual refill cart is provided with a surface to receive receptacles. This refill device is used when filling receptacles with drugs from inventory (e.g., in the hospital pharmacy). The manual refill cart may have on board electronic connections for facilitating communication between each receptacle and a computer in association with the cart.

The manual refill cart may have a bar code scanner attached to it to scan the bar codes on the unit dose packages of drugs to be loaded into the receptacle. The information from the bar coded packages of drugs is transferred from the bar code scanner and into the computer of the refill cart and/or into the memory chip of the receptacle. This enables the memory chip to maintain the information about the items stored in the receptacle.

The present invention overcomes many of the disadvantages of known approaches to drug distribution. There is no manual operation needed for bagging or unbagging medications at the nurses station for later use with patients. The receptacle of the present invention may arrive at the nurses station ready for use with patients without further handling of the drugs until administration to the patient. The receptacle also allows for fewer human errors in drug handling. In known systems, a drawer of drugs may open exposing several pockets with different drug varieties. With the preferred embodiment of the present invention only one receptacle opens at a time exposing only the drugs in that receptacle. Loading of receptacles is safer too. Since typically only one type of drug would be placed in each receptacle there is less chance that a person loading that one type of drug will accidentally load a second variety in the

same receptacle. Because the tops of the receptacles are preferably sealed closed until opened automatically upon receipt of an authorized signal at a delivery station, it greatly lessens the need for skilled staff to handle the receptacles. In other words, if the receptacle cannot be opened without proper receipt of signals from a delivery station, such as a dispensing machine, then there is less need to have sophisticated personnel for transport of the receptacles.

The present invention may also be an intelligent receptacle. In a preferred embodiment, information about the contents may be integral to the receptacle, such as by bar code or by electronic chip that is machine readable. This enables tracking of the contents, such as lot numbers and expiration dates of the contents, for example. When this information is ported to the dispensing machine and then to a central computer system, expiration dates of each drug in each receptacle may be monitored for replacement at the proper time.

A unique latch may also be employed with the receptacles. The latch may be comprised of bimetallic wire which contracts when it is heated by current. Upon contraction the wire pulls to one side and opens the latch allowing a spring to pop the lid open.

Several other features and advantages of the present invention will be readily apparent from the following detailed description of the invention, the attached drawings of the invention and the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a perspective view of a preferred embodiment of the receptacle of the present invention;

Fig. 2 shows a perspective view of the receptacle of Fig. 1, shown in an open top position;

Fig. 3 shows a partial, exploded view of the receptacle of Fig. 1;

Fig. 3A shows an enlarged, detailed view of a portion of the receptacle of Fig. 3;

Fig. 4 shows a plan view of a latch assembly of a preferred embodiment of the receptacle of Fig. 1;

Fig. 5 shows the latch assembly of Fig. 4, shown in the open position;

Fig. 6 shows a side elevation view of the latch assembly of Fig. 4;

Fig. 7 shows a perspective view of the latch assembly shown in Fig. 5;

Fig. 8 shows a perspective view of the receptacle of Fig. 1, shown from a bottom perspective view;

Fig. 9 shows a bottom plan view of the receptacle shown in Fig. 8;

Fig. 10 shows another embodiment of the present invention in which the receptacle shown in Fig. 1 is stacked on a similar receptacle;

Fig. 11 shows a side elevation view of the stacked receptacles of Fig. 10;

Fig. 12 shows a perspective view of another preferred embodiment of the present invention;

Fig. 13 shows a perspective view of the receptacle of Fig. 12, shown in the open top position;

Fig. 14 shows a perspective view of an embodiment of the present invention in which receptacles such as the receptacle shown in Fig. 1 are loaded into an automated dispensing machine;

Fig. 14A is an enlarged detailed view of a receptacle receiving location within the automated dispensing machine assembly shown in Fig. 14;

Fig. 14B shows an enlarged perspective detail view of a docking station of the automated dispensing machine assembly shown in Fig. 14;

Fig. 15 shows a partial perspective view of a drawer tray of the automated dispensing machine shown in Fig. 14.

Fig. 15A shows a detail plan view of a portion of the drawer tray shown in Fig. 15;

Fig. 15B shows a partial elevation view of a spring sub-assembly shown in Fig. 15A;

Fig. 16 shows a side elevation view of the insertion of a receptacle into a drawer of an automated dispensing machine;

Fig. 17 shows a side elevation view of the receptacle shown in Fig. 16, now fully inserted into the drawer;

Fig. 18 shows a side elevation view of the receptacle shown in Fig. 17, now released by the latch for removal;

Fig. 19 shows a perspective view of a drawer sub-assembly of the automated dispensing machine shown in Fig. 14;

Fig. 20 shows another perspective view of the drawer sub-assembly of Fig. 19, shown from a bottom perspective;

Fig. 21 shows a side perspective view of the drawer sub-assembly shown in Fig. 19;

Fig. 22 shows an electrical schematic of a preferred embodiment of the latch assembly of the receptacle of the present invention;

Fig. 23 shows a pictorial view of a plurality of nested receptacles, with one receptacle open, revealing its contents;

Fig. 24 shows a diagrammatical representation of a preferred system of the present invention;

Fig. 25 shows a diagrammatical representation of a second preferred system of the present invention; and

Fig. 26 shows a diagrammatical representation of a third preferred system of the present invention.

Fig. 27A shows the beginnings of four flow diagrams of a pharmacy preparation procedure that may have applicability to the present invention;

Fig. 27B shows the continuation of Figure 27A through a pick process that may have applicability to the present invention;

Fig. 27C shows the continuation of Figure 27B through a refill process that may have applicability to the present invention;

Fig. 27D shows another continuation of Figure 27B through a refill process that may have applicability to the present invention;

Fig. 27E shows another continuation of Figure 27B through a refill process that may have applicability to the present invention; and

Fig. 27F shows a continuation of Figures 27D and 27E through a return process that may have applicability to the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the Figures, there is shown in Fig. 1 a receptacle 30 of the present invention. The receptacle 30 has a plurality of sidewalls 32 that define a storage compartment 42 which is best shown in Figure 2. In Figure 2, a top 34 is opened and closed about a hinge 40. A latch assembly 38 is formed between the top 34 and one of the sidewalls 32 to keep the top in a closed position until an authorized operator gains access to the receptacle. The latch assembly 38 includes a latch member 44 and a latch receiving pocket 46.

The receptacle 30 may be used to contain various items, for example, medications. Each receptacle may house multiples of one type of drug or medical supply or it may house several varieties of drugs or medical supplies in the storage compartment 42. The receptacle of the present invention is adapted for use in a variety of systems. For example, it may be used at a patient's bedside table, on a medication cart, as a part of a drug administration kit in an operating room environment, or in many other scenarios both in and out of the medical industry. The invention has been described herein with reference to the medical industry but it is to be recognized that the invention has far reaching application in many industries.

The receptacle of the present invention may also be used as a removable return container for later disposing of items, such as used or discarded medicine administration items. The receptacle of the present invention may also be adapted for communication with one or more devices via one of several possible communication means. For example, the receptacle may communicate via a chip inside the receptacle that has been programmed with information, and the chip may be adapted for communication with another electronic device to download, or share the information. Another form of communication may be remote, such as via a RF proximity chip in the receptacle for RF communication with a RF station. Of course, the receptacle 30 may

also be "dumb," without on-board intelligence, and information about its contents may be contained within a bar code, for example, placed on the receptacle. In such an application of the invention, a receiving area of an apparatus, for example on or in an automatic dispensing machine, may acquire the necessary information through scanning of the bar code on the receptacle to enable the dispensing machine to know sufficient information about the contents of the receptacle. The receiving area may be a drawer in an intelligent dispensing machine having either an on-board computer processor or a connection to one remote therefrom.

In another embodiment, the receptacle **30** may have limited on-board intelligence. For example, the information storage device or the bar code label of the receptacle **30** may only contain information about the receptacle, such as the receptacle number (e.g., #1234567). This pre- programmed information would typically be entered when the receptacle **30** is filled. In this embodiment, a regular label (not a bar code label) or marking on the receptacle itself with the receptacle number may be used and the operator/user may manually enter the receptacle number into the computer having the pre-programmed information about the contents of the particular receptacle.

The receptacle **30** of the present invention may be refilled and reused many times in a preferred embodiment hereof. In a unique system of the present invention, a refill station may be provided for refilling each receptacle. If the receptacle is "intelligent", it may be programmed with information at the refill station and the refill station may be so adapted to provide this communication to the receptacle. The refill station may be at a pharmacy or at a distribution center in the application of this invention to the medical industry.

The receptacle 30 may be made from injection molded plastic, or formed from metal and as such, may be durable and reusable multiple times. Alternatively, the receptacle 30 may be made from inexpensive, disposable materials for discarding after use.

The receptacle 30, may also include a label 36 for identification of the contents within the receptacle and/or some or all of top 34 may be transparent. In Figures 3 and 3A, the receptacle 30 is shown in greater detail. The hinge assembly 40 includes a spring 48 and a pin 50 which join the receptacle compartment with the top 34. While a hinged top is preferred, a sliding top may be used. The receptacle 30 may further include a compartment 58 for housing a latch assembly 52. The latch assembly 52 may include a latch member 56 and a cover 54.

The latch assembly is shown in greater detail in Figures 4-7. Figure 4 shows the latch member 56 in a closed position while Figure 5 shows the latch member 56 in an open position. A switch 57 may electronically inform an automated dispensing machine computer that the top 34 is in an open or closed position. A memory chip 62 may store information concerning the receptacle. This memory chip 62 may store a wide variety of information, including the data in the Hearst Corporation's National Drug Data File, as shown in Table 1, such as expiration date, lot number, NDC number, type of drug or medical supply dosage, size of packages, number of items in the packages, etc. The memory chip 62 can also store information about the receptacle 30, including, when it was put in service, how many times it has been used, etc. This is beneficial because the receptacles 30 will have a limited useful life and it is desirable to take receptacles out of service before they fail (e.g., hinge breaks, latch breaks, etc.).

The receptacle 30 itself may be a medication package that contains drugs and a package insert. The receptacle 30 may replace bottles and other types of standard medication packages.

An electrical communication contact 66 enables connection from the receptacle to a receiving location within an automated dispensing machine, thus facilitating communication between the receptacle and the computer associated with the automated dispensing machine. When required signals are received at the electrical contact 66 from the automated dispensing machine, an electronic circuit, such as the one shown in Figure 22, actuates a muscle wire 64 causing the latch to be actuated and thus opening the top 34. The muscle wire works by receiving a current and upon increasing in temperature the wire 64 pulls to one side by shrinking and thereby causes the latch to be susceptible to a spring force acting upon it from a spring in the hinge assembly 40. The spring 48 pushes the top open when the latch is freed. In a preferred embodiment, the lid or top 34 will pop open about 15 degrees when the latch is opened.

An advantage of having the latch assembly as a separate component that can be removed from the receptacle 30 is that the latch assembly 52 and its components are more expensive and have a longer life expectancy than the storage compartment part of the receptacle 30. Therefore, the latch assembly 58 can be reused if the rest of the receptacle cracks or breaks (e.g., hinge breaks, etc.). The latch assembly preferably cannot be removed unless the top is opened.

Figures 8 and 9 show a bottom portion of the receptacle 30. Each receptacle may include legs 27, 29, 33 and 35 as well as a hook member 37 for engagement of the receptacle to a location, such as in an automated dispensing machine. Alternatively, the legs themselves may include catching or engagement features. An opening 39 enables contact by the electrical connection 66 with a port at the automated dispensing machine.

Figures 10-13 show other features of the present invention. In Figures 10 and 11, the receptacle 30 is shown stacked upon a similar receptacle 70. Legs 72 and 74 of receptacle 70

may be designed to reside within a location within an automated dispensing machine and/or within an area on a top surface of another receptacle. This allows for stacking of receptacles on each other for ease of storing and transportation. Figure 12 shows a double-wide receptacle **80** with top surfaces **82, 84** and latch **86**. Figure 13 shows the interior compartment of receptacle **80** as well as hinge assembly **88**. It is to be appreciated that the receptacles may come in a variety of sizes and shapes according to the particular use and storage location they are intended for. The receptacles are preferably modular in design to enable them to be used in combination, for example in a drawer of an automated dispensing machine, with several other similar receptacles, fitting in close proximity to one another to efficiently use the space available in each drawer.

Figures 14, 14A and 14B show views of the receptacles of the present invention installed within an automated dispensing machine **110**. Zones or locations **100** within a drawer **114** of the dispensing machine **110** are adapted to receive receptacles, such as receptacle **102**. A terminal display **112** may be provided with the machine **110** to enable an operator to review displayed information. A keypad **113** may be provided at the dispensing machine **110** to enter certain required information. A docking station **104** may be provided at the dispensing machine **110** for receiving receptacles, such as receptacle **102** within engagement receiver **126**, leg receivers **120, 122** and electrical port **124**. In this manner, each receptacle, such as receptacle **102**, may be docked at the machine **110** to enable certain information stored within the memory of the receptacle to be downloaded into a processor or computer associated with the machine **110**. If the receptacle **102** is to be loaded into a drawer **114** of the dispensing machine **110**, the drawer **114** may pop open to allow the receptacle **102** to be loaded into the correct zone **100** of the drawer **114**.

Within each drawer **114**, there may reside a tray **115** for holding receptacles **99**, etc. Individual zones **100** are adapted to receive individual ones of said receptacles. Spring assemblies **130, 128** function in a manner to be described hereinafter. The spring assembly **128** is shown in greater detail in Figure 15B to include springs **136** and **138**.

Zone **100** shown in Figure 15A also includes pockets **133, 135, 137** and **139** for receiving the legs of a receptacle. Figure 16, 17 and 18 show the insertion, locking, and release, respectively, of a receptacle **142** being placed into a drawer tray **115**. A nested or adjacent receptacle **140** is also shown already in place. Compression spring **143** is shown in its relaxed state in Figures 16 and 18 and is compressed and not in view in Figure 17. Latch member **145** is shown in cross section view in contact with electrical circuit **151**. Latch engagement member **150** is shown in Figure 16 in a position ready to receive the retaining hook **152** of engagement member **148** of receptacle **142**. As shown in Figure 17, when the engagement member **148** is depressed into the area **149** (shown in Figure 16), it catches or engages the end **154** of latching engagement member **150**. In Figure 18, latch engagement member **150** is actuated away from the engagement member **148** (moved to the right as shown in Figure 18), thereby releasing the connection between the engagement member **148** and the latch engagement member **150** which allows the spring **143** to return to its relaxed state pushing receptacle **142** up and out of zone **100** to enable an operator to remove the receptacle from the machine **110**. The actuation of the latch engagement member **150** away from the engagement member **148** may be done by a muscle wire mechanism such as in Figure 22 or by other suitable means.

Figure 19 shows a drawer **114** with a track **160** and rail **162** that is adapted to reside within the machine **110**. Wires **164** lead from a processor within the machine **110**, along, for

example, path 165 to each of the zones, such as zone 100, to carry communication between the receptacles 30 and the machine computer. Figures 20 and 21 show other views of the drawer 114. In Figure 21, a grid 168 may be installed along the rail 162 to be read by sensor 169 so that the computer aboard the machine 110 knows how far each drawer 114 has been pulled out of the machine, thereby exposing rows of receptacles 30. The sensor 169 may be an optical sensor or other suitable sensor adapted to read the bars or grids of 168 and communicate that information via wires 166 and through wires 164 to the computer. In another embodiment, RF communication links may be used instead of or in addition to, wires 166 and 164. In accordance with a preferred embodiment of the present invention, the drawer will be open before the top of the receptacle is popped open or the receptacle itself is popped up to be removed from the drawer.

Figure 22 shows a preferred embodiment of an electrical wiring circuit for use with the latch assembly of each receptacle 30. The circuit communicates with the muscle wire which controls the movement of the latch to enable the door to open on each receptacle. The inputs to the circuit may be from the computer onboard the machine 110. When an operator enters required information to access a receptacle, the computer may send the necessary signal to the receptacle via the circuit to open the latch. As stated above, the latch may be opened by spring force applied when the muscle wire retracts under current to free the latch for movement.

In one preferred embodiment of the latch assembly of the present invention a microprocessor is used. The microprocessor may include an analog to digital converter (A/D) and a pulse width modulator (PWM). The PWM produces a fixed frequency, variable duty cycle output. It is fed into a RC filter which produces a DC voltage between zero and five volts,

depending on the duty cycle. A voltage follower, n-channel FET, a bipolar transistor, or other kind of amplifier circuit is preferred to drive the muscle wire. The FET's are used to address a single muscle wire. The row drivers are p-channel FET's that supply the current generated by the voltage follower. The microprocessor outputs zero volts to the gate of the desired row and plus five volts to the rest. The column drivers are n-channel FET's that sink current to ground. The microprocessor outputs plus five volts to the gate of the desired column and zero volts to the rest. In a matrix of muscle wires, each wire has a diode in series with it to isolate it from the other muscle wires in the matrix. The current sense resistor generates a feedback voltage to the microprocessor proportional to the amount of current flowing in the muscle wire. The temperature sensor generates a voltage proportional to the ambient temperature.

The algorithm in the microprocessor is preferably structured as follows:

1. Select the desired row and column drivers.
2. Read temperature sensor.
3. Determine starting duty cycle and desired feedback target as a function of temperature (may be done via a look-up table).
4. Start the PWM generator.
5. Read the feedback voltage.
6. Compute error = (current feedback reading) - (desired target)
7. If error less than zero, the output current is too low, increase duty cycle.
8. If error greater than zero, the output current is too high, decrease duty cycle.
9. If error equals zero, do not adjust duty cycle.

10. If duty cycle cannot be increased, circuit may be broken. Shut off the PWM generator and report error to system.

11. If the duty cycle is below a predetermined threshold, there may be a short-circuit. Shut off the PWM generator and report error to system.

12. Check elapsed time since muscle wire was energized. If above desired time, shut off PWM generator.

13. Wait for PWM value to stabilize.

14. Go back to step 5.

Figure 23 shows a group of configured receptacles **170** and **180**, for example. The top **172** is open exposing the internal compartment **174** and in this example, syringes containing a predetermined drug **176** are shown inside the compartment **174**. Visible on the surface of each top of each receptacle is a label with printed drug information on the label as well as a bar code containing additional information about the item contained within that particular receptacle.

It should be appreciated from the foregoing description that the present invention is useful in the medical drug and supply field, however, the present invention has applicability to a broad range of industries apart from the medical industry, where similar inventory control and security measures are preferred. The present invention is not intended to be limited to the medical supply and drug industry.

Figures 24-26 show three (3) respective system diagrams for system implementations of the present invention beginning with a wholesaler all the way to a patient's bedside. As shown in Figure 24, the wholesaler receives the medications and fills the receptacles of the present invention with doses of the medications. These receptacles are then transferred to a pharmacy,

such as a hospital pharmacy, where they are next loaded into an automated dispensing machine. From the automated dispensing machine, the medications may be removed by appropriate personnel from the receptacles and administered to a patient at the patient's beside. The lower portion of the diagram of Figure 24 shows a flow of information from the automated dispensing machine to the various computer systems in communication with the computer of the automated dispensing machine. For example, as Figure 24 demonstrates, information concerning drugs administered to patients may be communicated to a hospital pharmacy computer, the wholesaler's computer, and the packaging company computer. Figure 25 shows a similar diagram, however, in this implementation, the receptacles are not filled prior to the drugs arriving at the automated dispensing machine. Instead, the receptacles are refilled at the automated dispensing machine and arrive at the automated dispensing machine in unit dose packs. Figure 26 shows another embodiment of a system of the present invention in which unit dose packs and prefilled receptacles are delivered to the automated dispensing machine where some previously existing receptacles at the automated dispensing machine are swapped for new receptacles.

Many advantages are derived from the receptacle of the present invention. Another advantage is seen from Figures 24-26. Due to the self-contained nature of each receptacle, much of the processing and handling of receptacles may be done automatically. For example, in Figure 24, an automated storage and transfer mechanism **200** may receive medications in packages and move the packages to a station where the receptacles are filled with the packages by robotics means.

Figures 27A through 27F show flow diagrams of preferred embodiments of the present invention whereby the receptacles, referred to as Cubies™ by the present inventors, are shown to be prepared at a pharmacy, through a pick process, a refill process, and a return process. Several possible modifications to these flow processes are able to be made without departing from the present invention. These flow diagrams are offered as an example.

Numerous modifications and variations in the invention are expected to occur to those skilled in the art upon considerations of the foregoing descriptions. The invention should not be construed as limited to the preferred embodiments and modes of preparation described herein, since these are to be regarded as illustrative rather than restrictive.